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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,747	03/22/2005	Robert H Shoemaker	015280-462100US	1785

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EXAMINER	
SNYDER, STUART	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
10/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,747	SHOEMAKER ET AL.	
	Examiner	Art Unit	
	Stuart W. Snyder	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *3-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 7-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the invention of Group I and the antimony species in the reply filed on 8/30/2007 is acknowledged. Claims 1,2 and 7-19 are pending and examined herein; claims 3-6 are withdrawn from examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17 recites the limitation "administered to an animal as a veterinary pharmaceutical formulation" in the second line. There is insufficient antecedent basis for this limitation in the claim. The claim depends on claim 15 and claim 15 is drawn to administration of the compound of claim 1 (as elected) to humans. Although humans are animals, there is no recitation of "animals" in claim 15.

3. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 improperly broadens the scope of claim 15 by reciting "animal", a genus of living creature that is broader than the species "human".

   Amendment of claim 17 to depend on claim 1 or claim 4 is one possible remedy to overcome these rejections.

Claim Rejections - 35 USC § 112

4. Claims 1-2, 7, 9-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an *in vitro* method involving two retroviruses, does not reasonably provide enablement for in vivo methods nor methods involving viruses other than retroviruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. It is well known in the art of drug development that most *in vitro* active compounds never achieve clinical use because of factors related to pharmaceutical availability, effective *in vivo* loss of activity because of protein attachment, rapid metabolism of the putative therapeutic and many others. Thus, in vitro activity *per se* does not enable *in vivo* use. Furthermore, the only two viruses tested were HIV-1 and MMLV both members of the gamma retrovirus family of retroviruses. It is not clear from the specification that the claimed virus inhibitors work in a method other than disrupting nucleocapsid assembly via interference with gag precursor protein and the viral genome. Because of the related structure of HIV-1 and MMLV, it is likely that the mechanism of virus replication inhibition is the same for the two viruses. In contrast to the two viruses tested, there are vast differences amongst the genus claimed—viruses. The claim reads on all viruses with no limitation on the structure or assembly mechanism of the viruses. It is highly unlikely that the claimed compounds, and hence the claimed method, would be effective against the such an array of viruses and the specification provides no such information.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 7-8, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wafsi and Johnson. The claims are drawn to a method of inhibiting replication of a virus comprising contacting a nucleocapsid protein of the virus with a compound having the recited formula consistent with substituted phenylstibonates (claim 1), the virus being a lentivirus (claim 7) or more specifically one of HIV or HTLV-1 (claim 8); claims 18 and 19 are drawn to the composition of claim 1.

Wafsi and Johnson teaches a method of inhibiting virus replication, specifically including HIV-1, by in vitro incubation of viral cultures with various compounds including the most basic compound of the series, $C_6H_5SbO_3H_2$, see page 116, Table 1. It is a necessary practice in antiviral testing to dissolve test compounds in aqueous, low concentration electrolytic solutions such as PBS or RPMI. Necessary characteristics of such solutions include low salt concentrations, neutral pH, sterility, and endotoxin free—e.g., characteristics that would make such formulation consistent with a pharmaceutical preparation with an excipient. Thus, Wafsi and Johnson teaches each and every limitation of claims 1, 7-8 and

18-19 and the claims are properly rejected under 35 U.S.C. 102(b) as being anticipated by Wafsi and Johnson.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 9, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wafsi and Johnson. The claims are drawn to *in vivo* use of the method in humans or animals. Although Wafsi and Johnson do not specifically teach *in vivo* use of the compounds tested, preclinical drug development is not performed in a vacuum. The ultimate goal of any *in vitro* drug program is to use the putative therapeutics clinically and *in vivo*. Thus, *in vivo* use of the claimed compounds in humans or in animals is obvious the person of ordinary skill in the art of drug development.

7. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wafsi and Johnson as applied to claims 1 and 7-8 above, and further in view of Hermans. Claims 10-14 are drawn to a method of inhibition of viral replication using the compound of claim 1 in combination with one or more additional anti-viral agents including nucleotide analogues, such as AZT or DDI, and/or protease inhibitors.

Hermans is a general review of the state of highly active antiretroviral therapy, HAART. Hermans teaches that it is desirable to include more that one therapeutic and especially combine different classes of anti-viral therapeutics in the treatment of primary HIV infection (PHI). In the section headed "Therapeutic Interventions for PHI", Hermans discusses the rationale for such combination therapy and specifically mentions AZT (Zidovudine), DDI as well as the desirability for inclusion of a protease inhibitor in HAART. As taught by Hermans, the clinical practitioner is motivated by the desire to reduce virus load and to increase the time until the virus mutates and becomes resistant to one or more components of the HAART as evidenced by so-called virus rebound.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder
Examiner
Art Unit 1648

SWS

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER